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Practitioner's Docket No. P1109

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of Jon M. Miller

Inventor(s)

for Prevention or Reversal of Weight Gain Associated with the use of Anti-  
Title of inventionPsychotic or Mood Stabilizing Drugs by Means of Histamine H<sub>2</sub>-Receptor Antagonists.  
**OR**

In re application of:

Application No.: 09 / 280,279

Group Art Unit: 1616

Filed: March 29, 1999

Examiner: Sharareh, S.

For:

Assistant Commissioner for Patents  
Washington, D.C. 20231TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. § 1.97(b).

## CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a))

I hereby certify that this correspondence is, on the date shown below, being:

## MAILING

☐ deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: 11/28/01

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Signature

Sherry A. Barnfield  
(type or print name of person certifying)

NOTE: The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).

### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

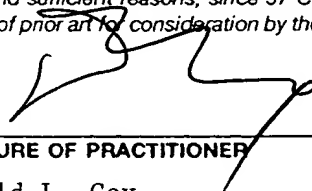
NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

  
SIGNATURE OF PRACTITIONER

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(type or print name of practitioner)  
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(Transmittal of Information Disclosure Statement Within Three Months of Filing or Before Mailing of First Office  
Action [6-3]—page 2 of 2)

#9



Practitioner's Docket No. P1109

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of Jon M. Miller

Inventor(s)

for Prevention or Reversal of Weight Gain Associated with the use of Anti-

Psychotic or Mood Stabilizing Drugs by Means of Histamine H<sub>2</sub>-Receptor  
Antagonists.

the specification of which is being transmitted herewith

OR

In re application of:

Serial No.: 09/280,279

Group No.: 1616

Filed: March 29, 1999

Examiner: Shanarah, S.

For:

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. 1.10\*

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Sherry A. Barnfield

(type or print name of person certifying)

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"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Information Disclosure Statement [8-1]—page 1 of 7)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
  - (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or
  - (3) Before the mailing date of a first Office action on the merits, whichever event occurs last."
- 37 C.F.R. 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).

### List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement; discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ EPO Search Report
  - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

**Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

SEE INFORMATION DISCLOSURE STATEMENT

# Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☒ supplied by the inventor(s).  
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. 1.56(c))  
☐ in the practitioner's file.

SIGNATURE OF PRACTITIONER

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Customer No.:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
Jon Miller

Serial No.: 09/280,279

Filed: 03/29/99

Attorney Docket No.: P1109

Art Unit: 1616

Examiner:

For: Prevention or Reversal of Weight Gain  
Associated with the use of Anti-Psychotic  
Or Mood Stabilizing Drugs by Means of  
Histamine H<sub>2</sub>-Receptor Antagonists.

HON. Commissioner of Patents & Trademarks  
Washington, DC 20231

**INFORMATION DISCLOSURE STATEMENT**

\* \* \* \* \*

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR §1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such. In accordance with 37 CFR §1.97(b), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56 (a) exists. This information is submitted in compliance with 37 CFR §1.98.

## References

### Parent Application

Application No.: 09/280,279 Substance to Prevent or Reverse Weight Gain Induced by Psychoactive Agents Filed 03/29/99 Jon M. Miller.

### Patents

Cottingham, et al., No.6,194,466 February 27, 2001, Use of Metformin to Counteract Weight Gain Associated with Valproate and Other Psychotropic Medications.

### Articles or other References

Masand PS. *J Psychotic Disorders*. 1998; 2(3): 4-6

Bymaster, et al. *J. Clin Psychiatry*. 1997; 58(suppl 10): 28-36

Kinon, BJ, Basson B, Szymanski K, et al., *Predictors of weight gain during olanzapine treatment*. *European Neuropsychopharmacology*. 1998; 8(suppl. 2):S220.

Stoa-birketvedt G., et al. *Acta Physiol Scan* 1997; 16(4): 489-94

Singh K, Singh PI. *Indian J Med Sci* 1995; 49 (11): 257-260

Physician's Desk Reference 52<sup>nd</sup> Ed. 1998: pp. 428-34, 1128-31, 1309-13, 1439-41, 1512-16, 1716-18, 1834-38, 1956-59, 2864-67

Physician's Desk Reference 53<sup>rd</sup> Ed. 1999: pp. 3428-32

Stephen Deutsch, Richard Rosse and Barbara Schwartz; *Histamine H<sub>2</sub>-Receptor Antagonists in Schizophrenia - Rationale for Use & Therapeutic Potential*; CNN Drugs, pp. 276-284, 10 (4), 1997.

Robert Leadbetter, et al., *Clozapine-Induced Weight Gain: Prevalence and Clinical Relevance*, *AMJ Psychiatry* 149:1 pp. 68-72, January 1992.

Trino Baptista, et al., *Glucose Tolerance and Serum Insulin Levels in an Animal Model of Obesity Induced by Sub-Acute or Chronic Administration of Anti-Psychotic Drugs*, *Prog. Neuro-Psychopharmacol & Bio. Psychiat.* Vol. 23 pp. 277-287, 1999.

Drug Facts and Comparisons, pp. 1198 and 2062, 1998 Edition.



Donna Wirshing, et al., *Novel Anti-Psychotics: Comparison of Weight Gain Liabilities*, J Clin Psychiatry,; 60:6, pp. 358-363, June 1999.

*Letters to the Editor*, Am J Psychiatry; 147:12, pp. 1693-1694, December 1990.

Jon M. Miller, *Reducing Weight Gain Associated with A-typical Anti-Psychotics*, Kentucky Psychiatrist, pp. 7-8, 11(1) Winter, 2000.

Carl Sherman, *H<sub>2</sub>-blocker Appears to Cut A-typical Weight Gain*, Clinical Psychiatry News pp. 1-2.

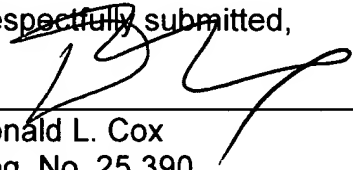
Ulcer Drug Reduces Weight Gain in Olanzapine Users.

David Ginsburg, *Nizatidine Treatment of Olanzapine-Induced Weight Gain*; Primary Psychiatry, pp. 17-20, 8 (6), 2001.

#### **Website Information**

Medlineplus Drug Information September 21, 2001.

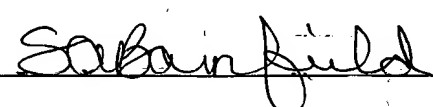
Respectfully submitted,

  
\_\_\_\_\_  
Donald L. Cox  
Reg. No. 25,390  
LYNCH, COX, GILMAN & MAHAN, P.S.C.  
400 West Market St, Suite 2200  
Louisville, Kentucky 40202

#### **CERTIFICATE OF SERVICE**

I hereby certify that this Information Disclosure Statement is being deposited with the United States Postal Service in an envelope addressed to the Hon. Commissioner for Patents, Washington, D.C. 20231.

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\_\_\_\_\_  
Sabina Field